UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,847	02/25/2004	David C. Gan	03.47	2937

23487 7590 04/02/2009

THE ESTEE LAUDER COS, INC
155 PINELAWN ROAD
STE 345 S
MELVILLE, NY 11747

EXAMINER	
VENKAT, JYOTHSNA A	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
04/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,847	GAN ET AL.	
	Examiner	Art Unit	
	JYOTHSNA A. VENKAT	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendment and IDS filed on 1/22/09. claims 2-4 and 17-19 have been canceled as per applicants' amendment dated 1/22/09.

Status of claims

Claims 2-12, 14-16, 17-19 and 20-24 are canceled. Claims 1, 13 and 25-26 are currently examined in the application.

Claim Rejections - 35 USC § 112

Claims 1 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". See ***In re Wands, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998).*** The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman, 230 USPQ 546*, the court recited eight factors

These factors include, but are not limited to:

1*) The breadth of the claims,*

2) The nature of the invention,

3) The state of the prior art,

4) The level of one of ordinary skill,

5) The level of predictability in the art,

6) The amount of direction provided by the inventor,

7) The existence of working examples

8) The quantity of experimentation needed to male or use the invention based on the content of the disclosure.

(1 and 2) The breadth of the claims and the nature of the invention: *The claims are drawn to:*

1. A method for increasing DNA synthesis of dermal papilla cells in hair follicles which comprises applying to the cells a composition containing creatine compound selected from the group consisting of cyclocreatine in an amount ranging from about 0.25mM to about 1mM.

13. A method for stimulating hair growth in hair plugs, which comprises applying to the hair plugs, a creatine compound selected from the group consisting of cyclocreatine in an amount ranging from about 0.25mM to about 1mM.

(3 and 5) The state of the prior art and the level of predictability in the art: *The art is unpredictable with respect to stimulating hair growth.*

(6-7) The amount of direction provided by the inventors and the existence of working examples

Specification under paragraph 21admits that certain concentration is effective in growing dermal papilla cells. See below.

[0021] Results: Creatine was found to significantly increase DNA synthesis in papilla cells (see Tables 1&2). At 0.25mM, creatine induced a 36% increase in DNA synthesis. At 0.5mM, creatine induced a 25% increase in DNA synthesis. At 1mM, creatine induced a 6% increase in DNA synthesis. Oxaloacetate was also found to significantly increase DNA synthesis in papilla cells in a dose dependent manner. At 0.25mM, Oxaloacetate induced a 22% increase in DNA synthesis. At 0.5mM, Oxaloacetate induced a 33% increase in DNA synthesis. At 1mM, Oxaloacetate induced a 38% increase in DNA synthesis. Positive results have also been observed with equivalent concentrations of AMP(1493% increase at .25 mM, 1930% at 0.5 mM, 1449% at 1 mM) and ATP(1413% increase at .25 mM, 1201% at .5 mM).

See below with respect to example 2.

[0023] Example 2. This example illustrates the increase in hair growth observed in hair plugs exposed to creatine.

[0024] Methods: Hair plugs were obtained from East Wood Medical Hair Transplant Surgery (Garden City, NY). These hair plugs were equilibrated in hair plug media as described in the literature (DMEM, 10% FBS, 1% PS, 25mg insulin, 25 µg fungizone). These hair plugs were measured under the microscope one the first day of arrival and treated with creatine at 1mM (n=6 for control and creatine group respectively). These hair plugs were then kept in the incubator at 37°C in 5% CO_2. On day 3, 7, & 10, re-treatments were made as well as measurements.

[0025] Results: The hair plugs were found to grow at a constant rate. In the untreated group, there was an average growth of 0.48mm at day 3 compared to day 0. There was an average growth of 0.73mm at day 7, and an average growth of 0.82mm at day 10. Creatine was found to significantly increase the growth rate of these hair plugs compared to the untreated plugs. There was an average growth of 0.95mm at day 3, 1.32mm at day 7, and 1.43mm at day 10 (Refer to Table 3, 4, and 5). These increases were all statistically significant.

[0026] Discussion: Creatine was found to significantly increase hair growth in hair plugs. This increase was nearly two fold compared to the untreated plugs. We previously observed creatine increasing DNA synthesis in dermal papilla cells. As dermal papilla cells influence and modulate the growth of hair, we postulate that creatine may be increasing hair plug growth by increasing the activity of dermal papilla cells.

Thus specification teaches that dermal papilla cell influence the hair growth. Test results showed that creatine induced 36% increase in DNA synthesis at 0.25 mM concentration. When the concentration was doubled there is 25% increase in DNA synthesis, and when the concentration was at 1 mM creatine induced 6% increase in synthesis. Therefore as the concentration of creatine increases the DNA synthesis value decreases. Test showed only values for creatine. The compound tested with respect to hair growth was in vitro and the results are with respect to creatine and not cyclocreatine. **There is no structural similarity between creatine and cyclocreatine**.

Regarding stimulating hair growth in hair plugs, test results at paragraph 24 used creatine at 1 mM concentration. At this concentration DNA synthesis was only 6%. *What is the reason for using this concentration, when the DNA synthesis is less compared to 0.25 mM concentration*? There is no correlation between the test results for DNA synthesis and stimulating hair growth in hair plugs. Stimulating hair growth was done using creatine and not any cyclocreatine compound. **There is no structural similarity between creatine and cyclocreatine**.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: the art is unpredictable with respect to hair growth. There is no correlation between the test results for DNA synthesis and stimulating hair growth in hair plugs. The instant specification gives one skilled in the art no indication that one could use cyclocreatine and increase DNA synthesis and stimulate hair growth in hair plugs and have a reasonable expectation of success. The instant specification gives one skilled in the art no indication that one could use cyclocreatine and stimulate the hair growth or increase DNA

synthesis. Therefore further testing would be necessary to use the claimed invention and the practice of the full scope of the invention would require undue experimentation with respect to cyclocreatine.

Response to Arguments

Applicant's arguments filed 1/22/09 have been fully considered but they are not persuasive.

Applicants' argue that the claims have been amended and the claims are in full compliance with 35 U. S.C. 112, first paragraph.

In response to the above argument, claims comply with 112, first paragraph with respect to creatine and creatine phosphate and not cyclocreatine. There is no structural similarity between creatine and cyclocreatine.

The following new ground of rejection is necessitated by IDS with a fee set forth under 1.17 (p). EP reference has been cited in the search report . Applicants' have not submitted a copy of this reference, therefore this reference is provided to applicants' and cited on PTO-892.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 13 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0565,010 ('010).

EP '010 teaches hair dye and hair growth compositions using creatine phosphate. See the abstract. See page 2, ll 40-55 and see page 3, ll 47-57 for the amount of cyclocreatine in 100 ml lotion. The difference between EP and instant application is EP doe snot teach creatine but creatine phosphate. Salt and its free form share close structural similarity. With respect increase in DNA synthesis of dermal papilla cells, admitted art at paragraph 6 teaches that increase in dermal papilla cells translates to increase in hair growth. EP teaches increase in hair growth and increase in hair growth is result of increase in DNA synthesis.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to use creatine phosphate for increase in hair growth and also use creatine for hair growth since creatine is the free form of creatine phosphate and increase in hair growth is result of increase in DNA synthesis of dermal papilla cells. It is a prima facie case of obviousness.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 1/22/09 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JYOTHSNA A VENKAT /
Primary Examiner, Art Unit 1619